P.O. Box 106 Barstow, CA 92312 May 19, 1999

4918 '99 MAY 24 11:59 Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane, Rm. 1061 Rockville, MD 20857-0003

Re: Docket No. 98N-1265

Dear FDA Officials,

It has recently come to my attention that the compounded drug that I receive by mail may no longer be available in the future unless a recent FDA memorandum of understanding (MOU) is amended. This MOU was written as a part of the FDA Modernization Act of 1997, Section 503A. I don't feel that this MOU accurately represents the original intent of Congress. It places unnecessary restrictions on consumer choices and commonly accepted professional pharmacy compounding practices.

It took me years to find a good pharmacy which would help me with my menopause symptoms. I wanted to use natural ingredients as an alternative to patented synthetics. Now, that I have a good working relationship with a mail-order pharmacy in another state, your MOU will remove my right to choose one of the best pharmacies available in the United States. I hereby protest!!!

I would like you to amend the MOU to remove the destructive wording. In its present form, the MOU, as well as the Compounding Section 503A of the Modernization Act, severely restricts the rights of physicians and patients to obtain healthcare products from the provider of our choice, and infringes on the rights of compounding pharmacies to serve the public's medical needs."

Sincerely

Jóvde Burk

Mrs. Joyce Burk P.O. Box 106 Barstow, CA 92312





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